



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

JUL 8 1987

OFFICE OF  
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

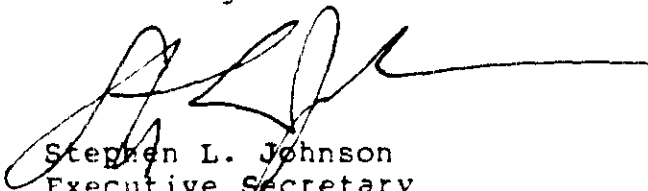
SUBJECT: Transmittal of the Final FIFRA Scientific Advisory Panel Reports on the June 25, 1987 meeting

TO: Douglas D. Campt, Director  
Office of Pesticide Programs (TS-766C)

The above mentioned meeting of the FIFRA Scientific Advisory Panel (SAP) was an open meeting held in Arlington, Virginia to review the following topics:

1. A Set of Scientific Issues Being Considered by the Agency in Connection with the Peer Review Classification of 2,4-D as a Class C Oncogen.
2. A Set of Scientific Issues Being Considered by the Agency on Aquatic Mesocosm Testing to Support Pesticide Registrations.

Please find attached the Panel's final reports on the two agenda items discussed at the meeting.

  
Stephen L. Johnson  
Executive Secretary  
FIFRA Scientific Advisory Panel (TS-769)

Attachments

cc: Panel Members  
John A. Moore  
James Lamb  
Al Heir  
Susan H. Wayland  
Anne Barton  
EPA Participants

FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

SCIENTIFIC ADVISORY PANEL

A Set of Scientific Issues Being Considered by the Agency in  
Connection with the Peer Review Classification of  
2,4-D as a Class C Oncogen

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The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP) has completed review of the data base supporting the Environmental Protection Agency's (EPA) preliminary decision to classify the peer review of 2,4-D as a Class C oncogen. The review was conducted in an open meeting held in Arlington, Virginia, on June 25, 1987. All Panel members were present for the review. In addition, Dr. John Doull, University of Kansas Medical Center, and Dr. Leon Burmeister, University of Iowa College of Medicine, served as ad hoc members of the Panel.

Public notice of the meeting was published in the Federal Register on Thursday, June 4, 1987.

Oral statements were received from staff of the Environmental Protection Agency and from Dr. David Serrone of RICERCA, Dr. Adalbert Koestner of Michigan State University, Dr. David L. Eisenbrandt of the DOW Chemical Company, Dr. Gregory G. Bond of the DOW Chemical Company, and Mr. Robert W. Morgan of the DOW Chemical Company, all representing the Industry Task Force on 2,4-D Research Data.

In consideration of all matters brought out during the meeting and careful review of all documents presented by the Agency, the Panel unanimously submits the following report.

REPORT OF PANEL RECOMMENDATIONS

Classification of 2,4-D as a Class C Oncogen

The Agency requested the Panel to focus its attention upon a scientific issue relating to the peer review classification of 2,4-D as a Class C oncogen. There follows the issue and the Panel's response to the issue:

Issue:

Does the Panel agree with the Peer Review Committee's conclusion concerning the Interim Category C classification of the available 2,4-D oncogenicity data?

Panel Response:

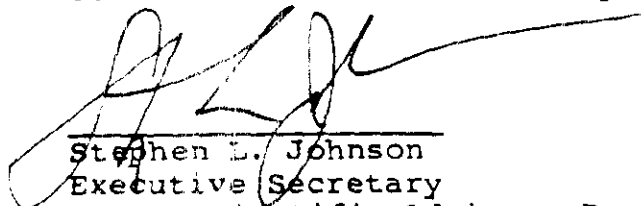
The SAP does not agree with the Peer Review Committee's conclusion that the available 2,4-D oncogenicity data should be classified as an Interim Category C (Possible Human Carcinogen). The Panel believes that the rat and mouse oncogenicity studies are adequate in design and conduct. The data are negative for oncogenicity in female rats and both sexes of mice. The increased incidence of astrocytomas in male rats exposed to 45 mg/kg 2,4-D was considered equivocal evidence of oncogenicity. The Panel believes that additional testing is required to resolve this issue. This testing should specifically address the astrocytoma issue by repeating an oncogenicity study. The study design should include two male rat control groups of 50 each and two male rat groups of the same size exposed to 45 mg/kg 2,4-D.

The Panel also believes that the human epidemiology studies represent well-designed and conducted investigations that present equivocal data on 2,4-D's oncogenicity for humans. Additional studies are underway that should help clarify the issue.

The Panel notes that equivocal evidence is different from limited evidence and that until additional data are developed it is improper to label 2,4-D as a carcinogen or a noncarcinogen. The Panel therefore concludes that the present data for animals and humans are inadequate for determining oncogenicity and that 2,4-D should be classified in Group D (Not Classifiable as to Human Carcinogenicity).

FOR THE CHAIRMAN:

Certified as an accurate report of Findings:

  
Stephen L. Johnson  
Executive Secretary  
FIFRA Scientific Advisory Panel

Date: 7/8/87

FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

SCIENTIFIC ADVISORY PANEL

A Set of Scientific Issues Being Considered by the Agency on  
Aquatic Mesocosm Testing to Support Pesticide Registrations

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The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP) has completed review of the Environmental Protection Agency's (EPA) proposed draft guidance document for Aquatic Mesocosm Testing to Support Pesticide Registrations. The review was conducted in an open meeting held in Arlington, Virginia, on June 25, 1987. All Panel members were present for the review, except Dr. James A. Swenberg.

Public notice of the meeting was published in the Federal Register on Thursday, June 4, 1987.

Oral statements were received from staff of the Environmental Protection Agency, Dr. John McCarthy of the National Agricultural Chemicals Association, Dr. Elliot B. Gordon of Makhteshim-Agan (America), Inc., and Dr. Jeffrey M. Giddings of Springborn Life Sciences, Inc.

In consideration of all matters brought out during the meeting and careful review of all documents presented by the Agency, the Panel unanimously submits the following report.

REPORT OF SAP RECOMMENDATIONS

Aquatic Mesocosm Testing to Support Pesticide Registrations

The Agency requested the Panel to focus its attention upon a set of issues relating to the proposed draft guidance document on Aquatic Mesocosm Testing to Support Pesticide Registrations. There follows a list of the issues and the Panel's response to the issues:



13544

R145287

Chemical: 2-4,D

PC Code:  
030001

HED File Code: 11000 Chemistry Reviews  
Memo Date: 7/8/1987  
File ID: 00000000  
Accession #: 000-00-0119

*HED Records Reference Center*  
5/31/2007

